Consent Form for UTIMPRO test

Intended for adults agreeing their biological samples (endometrial biopsies) to be studied
For the assessment of uterine receptivity before ART

This innovative approach by collecting biological samples (endometrial biopsies) and data study is organized by the Innovation Society *MatriceLAB Innove* .

The purpose of this test recommended by your doctor is to document the immune environment of the uterus during the receptive period of the cycle (i.e. when the endometrium is susceptible to allow the implantation of an embryo, or *the implantation window* during mid luteal phase).

This assessment is based on the diagnosis of a local immune imbalance which may interfere with the embryo implantation; schematically, to determine an insufficient or an excessive immune activation in the endometrium.

The identification of the immunological mechanisms involved is based on the quantification by molecular biology of endometrial biomarkers (specific cytokines and modulators) regulating uterine immune cells.

Given these data, your doctor may consider to modulate and personalise your next treatment to counter the potential identified local immune imbalance.

As part of this innovative approach, we ask for your consent:

1.To enable us to run a data study to assess the impact of this new diagnostic approach in Reproductive Medicine. In this view, we will potentially have to contact your doctor to determine the outcome of your treatment, pregnancy and birth at the end of your next attempt. Your medical information is subject to data processing and you have rights of access and correction with Dr. Nathalie Ledee (France) who heads *MatriceLAB Innove*

☐ I agree ☐ I disagree

2. To enable us to keep the biological samples.
In the context of data assessment, the biopsies will be frozen and stored for 5 years on *MatriceLAB Innove* site located in Pépinière Bio&D in Creteil, under the responsibility of Dr. Nathalie Ledee, and destroyed after the study outcome. Independently from your personalised diagnostic test, they may be used for technical improvement or identification of new complementary biomarkers to increase the accuracy of our diagnosis. The data collected will be kept strictly confidential and they may only be consulted by the medical team, the people duly mandated and possibly by local representatives of health and judicial authorities empowered.

☐ I agree ☐ I disagree

Date of consent: .....

Patient's name: ..... **Patient's signature: .....**

Consultant's name: ..... **Consultant's signature: .....**